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Association between sleep quality and cardiovascular disease in maintenance hemodialysis patients: a prospective cohort study

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ABSTRACT

Objective: This study aimed to analyze the association between sleep quality and cardiovascular disease in patients on maintenance hemodialysis (MHD).

Methods: A total of 601 patients with MHD in the second affiliated hospital of Nanjing Medical University, were prospectively enrolled in this cohort study from January 2019 to December2019. The global Pittsburgh sleep quality index (PSQI) score > 7 indicates that a person with poor sleep quality. Patients were divided into two groups according to the PSQI score. Follow-up was conducted about 3 years with all-cause death and major adverse cardiovascular events (MACEs) as the endpoint events.

Results: Of the 601 patients, 595 patients completed the PSQI assessment, with 278 patients having poor sleep quality. Patients in the PSQI > 7 group were older and had a higher proportion of cardiovascular disease or diabetes. Years of education, diastolic blood pressure, and heart rate were lower in the PSQI > 7 group. At a mean follow-up period of 3 years, 116 patients died, 64 patients were lost to follow-up, and 115 patients experienced MACEs. After adjusting for confounding factors such as age, gender, dialysis age, and previous cardiovascular disease, the risk of MACE in patients with poor sleep quality was twice that of patients with good sleep quality (HR = 2.037 (1.339, 3.097), $p = 0.001$). There was no significant difference in the risk of all-cause death between the two groups.

Conclusion: The prevalence of poor sleep quality was 46.7% in patients with MHD. Poor sleep quality was an independent risk factor for MACEs in patients with MHD.

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Introduction

Most patients undergoing maintenance hemodialysis (MHD) have sleep disorders [1–3], including insomnia, restless legs syndrome, periodic limb movements during sleep, and sleep apnea [1]. Studies have shown that poor sleep quality is associated with a variety of diseases, such as diabetes, cardiovascular disease (CVD), stroke, anxiety, and depression [4–7]. The early Dialysis Outcomes and Practice Patterns Study (DOPPS) revealed that poor sleep quality increased the risk of all-cause mortality in patients on hemodialysis [8], and the studies conducted by Brekke et al. and Han et al. had shown similar conclusion [9,10]. Shoji et al. also displayed that reduction of poor sleep quality is independently associated with a higher rate of new-onset of CVD events [11]. However, Harris et al. found that sleep quality was not associated with the risk of death in patients on hemodialysis [12]. The inconsistency between these findings may be related to differences in the methods used to evaluate sleep, race of the study population, duration of follow-up, and medical conditions. Moreover, few studies have investigated sleep quality in the population of Chinese patients on hemodialysis [10].

Cardiac deaths account for 50% of deaths in patients with end-stage renal disease [3,13], and the severe burden caused by CVD is a major factor affecting the prognosis of patients on dialysis. Given the prevalence of CVD, its life-threatening consequences, and the lack of effective interventions, the Standardized Outcomes in Nephrology-Hemodialysis study (MINOCA) suggested including myocardial infarction (MI) and sudden cardiac death as core cardiovascular outcome measures [14]. Major adverse cardiovascular events (MACEs) include sudden cardiac death, nonfatal MI, stroke, and the need for revascularization [15–17]. A study conducted in patients with MI with non-obstructive coronary arteries showed that sleep quality was associated with the risk of

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developing MACEs [15], and another study in patients with obstructive sleep apnea revealed that hemoglobin level and nocturnal hypoxia were independent risk factors for developing MACEs [18]. However, various clinical studies excluded patients on dialysis because of their distinct pathophysiological changes, such as the accumulation of uremic toxins, disturbances in calcium and phosphate metabolism, and vascular calcification, that differentiate them from the general population [19–21]. Thus, the correlation between measured sleep quality and the incidence of MACEs in patients on dialysis requires further elucidation.

In this study, we prospectively enrolled a cohort of patients on MHD, collected their baseline demographic and clinical data, and assessed their sleep quality for a follow-up period of approximately 3 years. We posited that poor sleep quality is associated with a high risk of cardiovascular disease in patients undergoing MHD.

Materials and methods

Study population

This study is a single, prospective cohort study conducted in the Second Affiliated Hospital of Nanjing Medical University. We included all adult patients (over 18 years old), who received hemodialysis (HD) for more than 3 months from 1 January 2019 to 31 December 2019. Exclusion criteria included unstable conditions (malignant hypertension, acute infection, etc.), malignancy or surgery, and those plan to receive kidney transplantation or transfer to other dialysis centers or change to peritoneal dialysis treatment within the next year. The study was approved by the institutional research ethics committee of The Second Affiliated Hospital of Nanjing Medical University (ID: [2018]KY116), and all participants were able to give informed consent.

Basic information collection

Demographic, medical information, clinical and laboratory information were extracted from the patients' medical records by trained research staff. Laboratory data were obtained within 3 months before enrollment.

Assessment of sleep quality

We assessed sleep quality using Pittsburgh sleep quality index (PSQI) self-rated questionnaire. The PSQI has 19-items that are divided into seven components including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. The each of the seven components is scored from 0 to 3, with a total score ranging from 0–21. The global score ≥7 indicated poor sleep quality [22–24]. All patients performed questionnaire at the time of enrollment. When patients had visual and hearing impairments, the accompanying staff answered on their behalf.

Follow-up and outcomes

Participants were followed up half-yearly in the first 3 years until 31 December 2022. The primary outcomes were all-cause mortality and major adverse cardiovascular events (MACEs). The definition of MACE had been reported in detail previously [25]. The survival time (months) was defined as the interval from the time of enrollment to the date of death or last visit. An Endpoint Committee consisting of three senior physicians was responsible for reviewing and adjudication of reported end point events, and confirmation of an event required agreements of at least two committee members.

Statistical analyses

Continuous variables were expressed as mean ± standard deviation or median (interquartile range) and categorical variables were expressed as counts (%). Numerical variables with a skewed distribution were logarithm transformed in further analysis if needed. Survival analysis was estimated by the Kaplan–Meier test and tested by a log-rank test. Univariate and multivariate Cox regressions were used to assess the relationship between independent variables and survival. All analyses were performed using SPSS 25.0. A 2-tailed p value < 0.05 was considered statistically significant.

Results

General characteristics of the patients

A total of 601 patients on MHD were enrolled in this study, as 595 completed the sleep quality questionnaire (Figure 1). The clinical characteristics of the cohort and the distribution of PSQI score are shown in Table 1 and Figure 2A. Among these 595 patients, the mean age was (57.40 ± 13.72) years and 350 (58.8%) were male individuals. Patients were divided into two groups based on their PSQI score. Patients with a PQSI score of ≤7 were assigned to the group with good sleep quality, while those with a PSQI score of >7 were assigned to the group with poor sleep quality. The Distribution of subgroups of PSQI scores in the two groups were shown in Supplementary Table 1.

As shown in Table 1, the patients in the poor sleep quality were significantly older, had a higher proportion of cardiovascular disease or diabetes, had lower educational levels, lower heart rate, and lower diastolic blood pressure. There were no significant differences between the PSQI ≤ 7 and PSQI > 7 groups in terms of the sex ratio, body mass index (BMI), proportion of patients who smoke, proportion of patients maintained on statin therapy, time on dialysis, interdialytic weight gain (IWG), systolic blood pressure, hemoglobin level, calcium level, phosphate level, and parathyroid hormone (PTH) level. In addition, fluid assessment by bioimpedance spectroscopy was performed in 362 of 595 patients. Fluid status in dialysis patients was also comparable between the two groups (Supplementary Table 2).

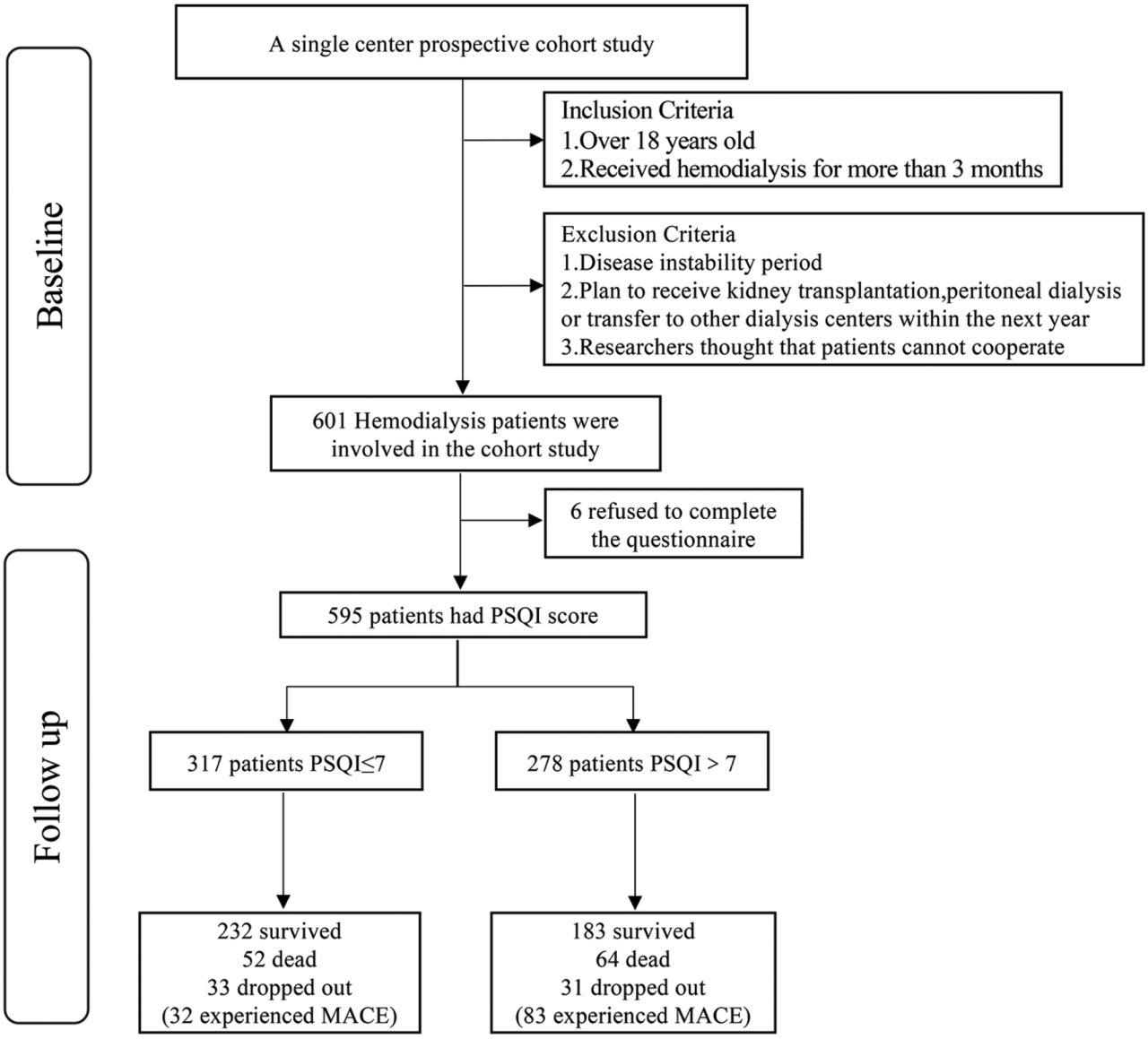

Figure 1. Flow diagram of the study.
Cohort flowchart of the enrollment, allocation, and 3-years follow-up of this study. PSQI: Pittsburgh sleep quality index; MACE: Major adverse cardiovascular events

Factors influencing the PSQI score

As shown in Figure 2B, gender had no significant effect on sleep quality. However, the proportion of patients with poor sleep quality increased with age (Figure 2C). Additional Logistic regression analysis showed that age, cardiovascular disease, diabetes were significant influencing factors of poor sleep quality in MHD patients (all $p < 0.05$) (Table 2).

Follow-up and endpoint events

The median follow-up time was 3 (2.5–3.7) years, during which 64 patients were lost to follow-up (10.8%) and 116 patients died (19.4%). 57 patients died from cardiovascular causes (including acute coronary syndrome, heart failure, and sudden cardiac death), 15 patients died from cerebrovascular events, and 44 died from other diseases. In the PSQI > 7 group, 83 patients experienced MACEs, whereas in the PSQI ≤ 7 group, 32 patients experienced MACEs.

Effect of sleep quality on all-cause mortality

Kaplan–Meier survival curve analysis of the effect of sleep quality on the prognosis of patients on dialysis suggested a significant difference in all-cause mortality between the PSQI > 7 and PSQI ≤ 7 groups, with shorter patient survival time ($p = 0.031$) in the PSQI > 7 group (Figure 3A). Univariate Cox regression analysis (Model 1) showed that patients with poor sleep quality had a 49% higher risk of mortality [hazard ratio (HR)=1.490, 95% CI (1.033 to 2.148), $p = 0.032$]. In the multivariate Cox regression analysis, we adjusted Model 2 for age, sex, and time on dialysis or adjusted Model 3 for age,

Table 1. Baseline characteristics of the patients.

	Total ($N=595$)	PSQI ≤ 7($N=317$)	PSQI > 7($N=278$)	P
Age, years	57.40 ± 13.72	54.71 ± 14.01	60.58 ± 12.71	**< 0.001**
BMI, kg/m^2	23.07 ± 3.64	23.08 ± 3.82	23.06 ± 3.41	0.940
Education year, years	9.28 ± 4.24	9.63 ± 4.16	8.87 ± 4.27	**0.028**
Male, n (%)	350 (58.8%)	185 (58.4%)	165 (59.3%)	0.806
Current Smoker, n (%)	165 (27.7%)	85 (26.8%)	80 (28.8%)	0.233
CVD	173 (29.1%)	70 (22.1%)	103 (37.1%)	**<0.001**
Diabetes	193 (32.4%)	85 (26.8%)	108 (38.8%)	**0.002**
Statins	71 (11.9%)	32 (10.1%)	39 (14.0%)	0.140
Dialysis duration, month	55 (20, 121)	62 (20, 119)	53 (19, 123.0)	0.926
IWG, kg	2.22 (1.71, 2.72)	2.22 (1.73, 2.72)	2.20 (1.70,2.72)	0.439
SBP, mm Hg	141.74 ± 28.12	141.85 ± 24.54	142.19 ± 30.66	0.881
DBP, mm Hg	81.88 ± 16.05	83.89 ± 14.49	79.83 ± 16.73	**0.002**
Heart rate, bpm	77.87 ± 13.35	79.40 ± 11.66	76.38 ± 14.22	**0.005**
Hemoglobin, g/L	106.47 ± 15.98	107.04 ± 16.36	105.88 ± 15.70	0.382
Calcium, mmol/L	2.22 ± 0.22	2.21 ± 0.23	2.23 ± 0.21	0.398
Phosphorus, mmol/L	1.75 ± 0.57	1.75 ± 0.57	1.75 ± 0.57	0.896
PTH, pg/mL	169.4 (58.9, 344.9)	172.9 (57.2, 334.3)	166.5 (61.3, 350.8)	0.918

Values are presented as mean ± SD for normally distributed or median [IQR] for skewed variables, and as count (percentage) for categorical variables.

Abbreviations: BMI: Body Mass Index; CVD: Cardiovascular disease; IWG: Interdialytic weight gain; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; PTH: Parathyroid hormone.

gender, dialysis duration, education, IWG, previous cardiovascular disease, diabetes, hemoglobin, systolic blood pressure, diastolic blood pressure, and heart rate, there was no significant difference in all-cause mortality between the two groups [HR = 0.851 (0.584-1.240), $p=0.400$] (Table 3, left)

Effect of sleep quality on MACE

Kaplan-Meier event-free survival curve for occurrence of MACE in patients with hemodialysis suggested a significant difference in the incidence of MACEs between the PSQI > 7 and PSQI ≤ 7 groups, with higher risk of MACEs ($p<0.001$) in the PSQI > 7 group (Figure 3B). Univariate Cox risk regression analysis showed (Model 1) that patients with poor sleep quality had a 221.3% higher risk of MACEs [HR = 3.213, 95% CI (2.136 to 4.831), $p<0.001$] than those with good sleep quality. In the multivariate Cox regression analysis, we adjusted Model 2 for age, sex, and time on dialysis and found that the risk of MACEs was also higher in patients with poor sleep quality [HR = 2.418, 95% CI (1.599 to 3.658), $p<0.001$] than in those with good sleep quality. Based on Model 2, Model 3 was adjusted for years of education, IWG, comorbid CVD, comorbid diabetes, systolic blood pressure, diastolic blood pressure, and heart rate. The results showed that poor sleep quality was an independent risk factor for the incidence of MACEs in patients on dialysis (HR = 2.037, 95% CI 1.339 to 3.097, $p<0.001$) (Table 3, right). Furthermore, Model 3 combined adjusted with fluid overload also showed the same results (Supplementary Table 3). We also analyzed the associations of PQSI with MACE across certain subgroups, including age (>60 vs. ≤60), diabetes (yes vs no) and previous history of cardiovascular disease (yes vs no). Forest plots from subgroup analysis showed that the association between poor sleep quality and MACE was not existed among subgroups in patients with a history of diabetes or cardiovascular disease (Supplementary Figure 1).

Discussion

A brief summary

A growing number of studies show that sleep quality is closely related to people's health, affecting the occurrence and progression of a variety of diseases such as tumors, metabolic diseases, including kidney diseases [26–30]. In this single-center prospective cohort study, we found that sleep quality was significantly associated with the long-term prognosis of patients on dialysis, and patients with poor sleep quality had a significantly higher risk of MACEs than those with good sleep quality. This finding suggests that we may need to pay more attention to the sleep quality of patients during dialysis and to intervene promptly to improve their long-term prognosis.

Comparison of our results with the existing literature

This study revealed that almost half of the patients had sleep disorders, which is similar to the prevalence reported by Elder et al. (46.7% vs. 49%) [8] but different from the findings of Cengić et al. (73.5%) [31] and Brekke et al. (74.3%) [32]. The inconsistency between these results could be due to the different criteria used to define poor sleep quality (PSQI score of >5) and differently designed questionnaires used to assess sleep quality; 60.7% of patients would be assessed to have poor sleep quality if we used a more stringent cutoff PSQI value (i.e., a score of >5). Overall, we need to pay extra attention to the quality of sleep of patients on hemodialysis [33]. Our study revealed that age, comorbid CVD, and comorbid diabetes were independent influencers of sleep quality, while sleep quality was not associated with BMI, sex, interdialytic weight gain, calcium level, phosphate level, or PTH level. This is generally consistent with the findings of previous studies. Cengić et al. found that patients with poor sleep quality were older and had lower hemoglobin levels, whereas BMI,

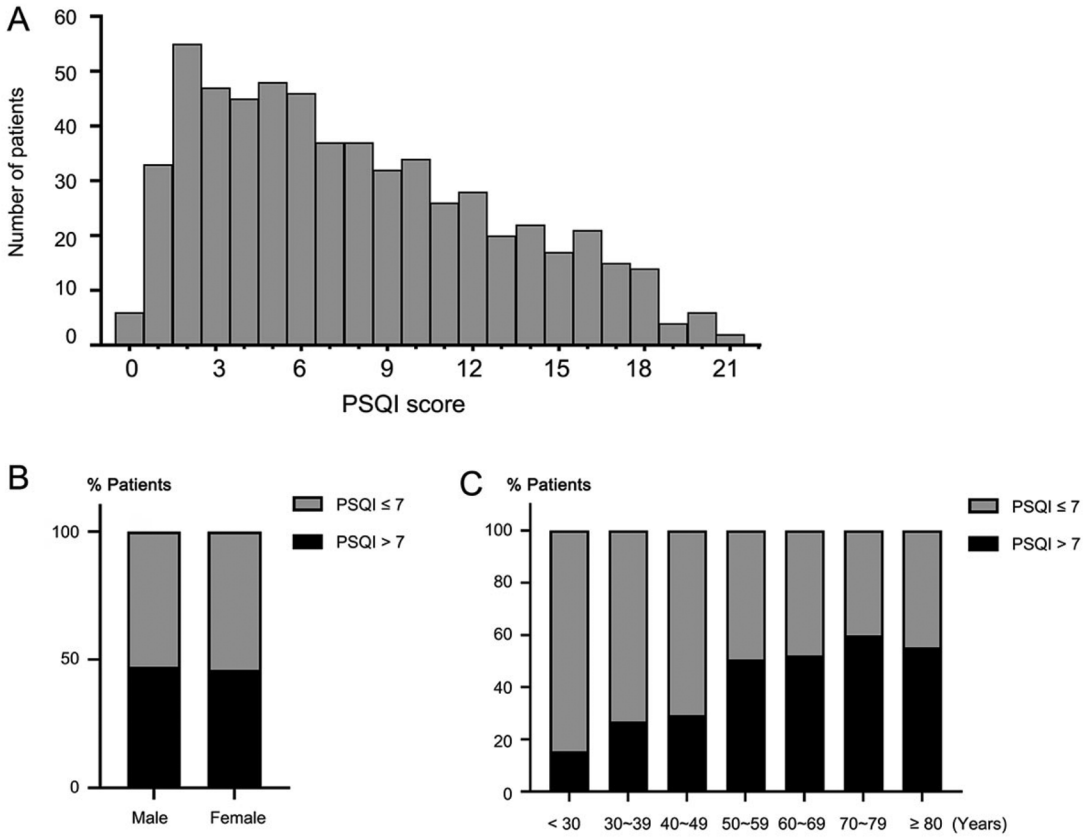

Figure 2. Frequency of poor sleep quality in dialysis patients.
(A): The distribution of PSQI score in dialysis patients; B: The frequency of poor sleep quality (PSQI score of >7) in dialysis patients by sex; C: The frequency of poor sleep quality in dialysis patients among different age group. PQSI: Pittsburgh sleep quality index.

Table 2. Binary logistic regression analysis of sleep influencing factors.

	Exp	*95%CI*	*P*
Sex(male/female)	1.119	0.768, 1.629	0.559
Age, years	1.025	1.009, 1.041	**0.002**
Dialysis duration, month	1.002	0.999, 1.004	0.215
Education year, years	0.977	0.934, 1.023	0.321
IWG, kg	1.008	0.788, 1.291	0.948
Hemoglobin, g/L	0.996	0.985, 1.007	0.467
Calcium, mmol/L	1.726	0.805, 3.700	0.161
Phosphorus, mmol/L	1.334	0.956, 1.863	0.090
PTH, pg/mL	1.000	0.999, 1.001	0.986
BMI, kg/m^2	0.979	0.932, 1.029	0.399
DBP, mm Hg	0.997	0.984, 1.010	0.623
Heart rate, bpm	0.991	0.976, 1.006	0.230
Diabetes(yes/no)	1.553	1.036, 2.328	**0.033**
CVD (yes/no)	1.563	1.043, 2.340	**0.030**

Abbreviations: IWG: Interdialytic weight gain; PTH: Parathyroid hormone; BMI: Body Mass Index; DBP: Diastolic blood pressure; CVD: Cardiovascular disease.

phosphate levels, and PTH levels were not associated with poor sleep quality. [31]. Elder et al. found that poor sleep quality was associated with coronary heart disease, diabetes, psychological disorders, and peripheral vascular disease [8]. The mean age of patients on dialysis in our center was 57.4 years, and we found that the proportion of patients with poor sleep quality increased gradually with age, with up to 60% aged 70–79 years having sleep disorders. Older patients are more likely to have problems with sleeping than younger patients, which may be related to the presence of multiple comorbidities, administration of multiple medications, and changes in lifestyle [34]. In addition, the levels of calcium, phosphorus, PTH, and hemoglobin did not differ between the two groups of patients in our dialysis center, and this finding may be related to the improvement in dialysis quality control in recent years.

Elder et al. and Han et al. found 16% and 1.96-fold increase, respectively, in the risk of all-cause mortality in patients with poor sleep quality [8,10]. However, Harris et al. found no association between sleep quality and the survival rate [12]. We found a 49% increase in the risk of mortality in patients with poor sleep quality, whereas there was no difference in the survival rate between the two groups of patients after the inclusion of confounding factors, such as age, sex, and time on dialysis, in the analysis. These inconsistencies may be related to the differences in the duration of the follow-up period and those in the questionnaire used to evaluate sleep quality. We also found a strong correlation between sleep quality and the risk of developing MACEs. Zhu et al. found that poor sleep quality led to a 96.7% increase in the risk of developing MACEs in patients with non-obstructive MI (HR = 1.967, 95% CI 1.442 to 3.639) [15]. Zhao et al. studied 412 patients with ST-segment-elevation MI for 5 years and found that working night shifts increased the severity of their MI and risk of developing MACEs by 92%

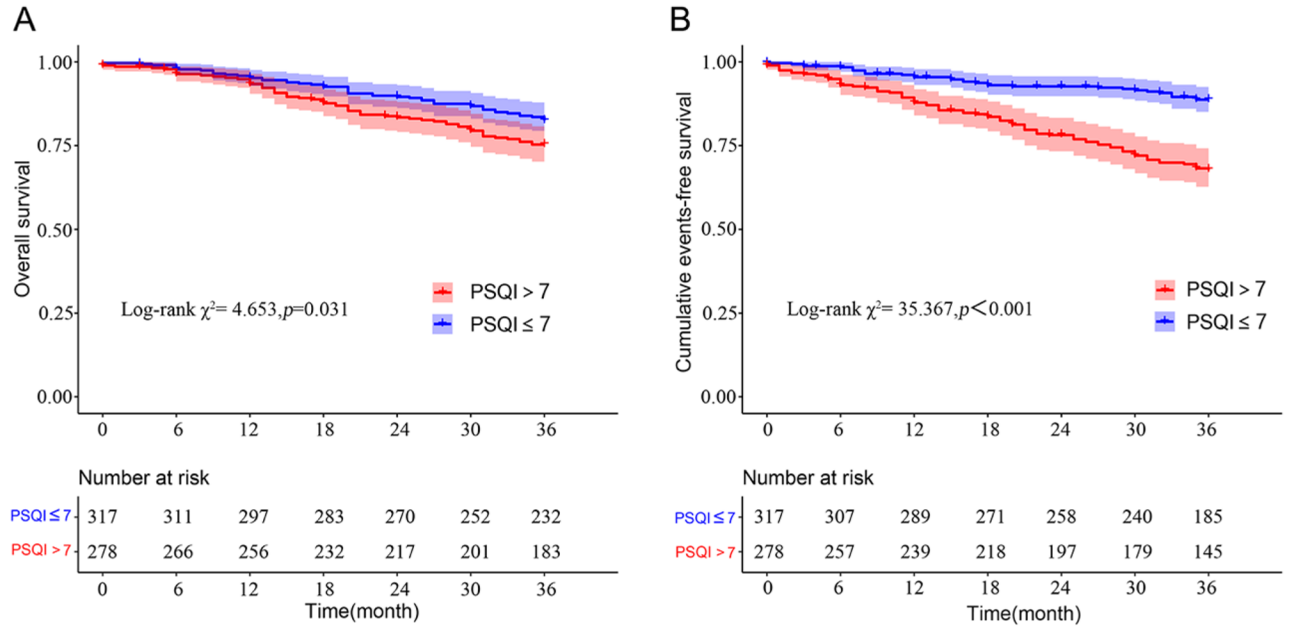

Figure 3. Kaplan-Meier survival curves at 3-year follow-up.
A: Kaplan-Meier survival curves at 3-year follow-up for all-cause mortality in hemodialysis patients grouped by PQSI; B: Kaplan-Meier event-free survival curve for occurrence of MACE in hemodialysis patients grouped by PQSI. *p* value indicates the log-rank test. PSQI: Pittsburgh sleep quality index; MACE: Major adverse cardiovascular events.

Table 3. Multivariate cox regressions for the associations of PQSI with all-cause mortality or MACE.

	All-cause death		MACE	
	HR	*P*	HR	*P*
Model 1	1.490 (1.033, 2.148)	**0.032**	3.213 (2.136, 4.831)	**< 0.001**
Model 2	0.995 (0.686, 1.442)	0.977	2.418 (1.599, 3.658)	**< 0.001**
Model 3	0.851 (0.584, 1.240)	0.400	2.037 (1.339, 3.097)	**0.001**

Model1: unadjusted.
Model2: adjusted for age, sex, dialysis vintage.
Model3: adjusted for age, sex, dialysis vintage, Education year, CVD, DM, Hemoglobin, SBP, DBP, HR.
Abbreviations: CVD: Cardiovascular disease; DM: Diabetes mellitus; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HR: Heat rate.

(HR = 1.92, 95% CI 1.12 to 3.29), and these findings have been validated on animal models [35]. The association of poor sleep quality assessed by PSQI scores and MACEs was also found in patients with diabetes, HIV, or polycystic ovary syndrome [36–38]. However, the association between sleep quality and the incidence of MACEs in patients with MHD has not yet been described. It has been found that disturbances in the circadian rhythm led to reduced expression of the nuclear receptor subfamily 1 group D member 1, which in turn elevates the level of cardiotrophin-like cytokine factor 1 in the myocardium, increasing the inflammatory response and damaging the heart [35]. It was verified that sleep quality was associated with activity of Crohn's Disease [39]. In addition, dysbiosis of gut microbiota, accumulation of uremic toxins, such as indoxyl sulfate and kynurenine, and destruction of blood vessel walls have been found in patients with renal failure, leading to the incidence of adverse cardiovascular events [40,41]. This may be related to the fact that sleep disorders affect the metabolism of gut microbiota and increase the accumulation of indoles. The levels of uremic toxins and tryptophan metabolomics to explore potential mechanisms for the high risk of MACEs in patients with poor sleep quality need further investigation.

Limitation

This study has some limitations. This study is a single-center prospective cohort study with a relatively short follow-up period. In this study, we assessed sleep quality using the PSQI, which only reflects sleep quality in recent months and is susceptible to subjective influence by factors, such as mood, anxiety, and depression. The level of 25(OH)D, albumin and B-type natriuretic Peptide (BNP)were not collected, and fluid assessments were not completed for all patients. Then, we did not compare the sleep quality of chronic kidney disease with or without HD. Lastly, the study focused on dialysis patients, findings in other populations require further study. Thus, future multicenter studies with larger sample sizes, longer follow-ups, and more accurate tools for assessing sleep quality are needed to further elucidate the impact of sleep quality on the prognosis of patients on dialysis.

In conclusion, this study aimed to investigate the correlation between sleep quality and the prognosis of patients on MHD. The results showed that 46.7% of patients had poor sleep quality, with age, comorbid CVD, and comorbid diabetes being identified as influencers of sleep quality. After adjusting for confounding factors, such as age, sex, time on dialysis, and comorbid CVD, the risk of MACEs in patients with poor sleep quality was approximately two times higher than that in those

with good sleep quality, suggesting that improving the sleep quality of patients on dialysis may reduce the risk of MACEs. The findings of our study need to be further validated in more cohorts of patients on dialysis. Moreover, there is still an urgent need for basic research to further unravel the pathophysiological mechanisms by which poor sleep quality leads to the development of MACEs in patients on dialysis.

Authors' contributions

Lei Jiang, Hong Ye, and Junwei Yang were involved in the research idea and study design. Han Tian, Lulu Wang, Qingyu He, Xinxin Xu, and Yan Zhang were responsible for data acquisition. Han Tian and Lulu Wang were involved in data analysis and interpretation. Lei Jiang, Hong Ye, and Junwei Yang were involved in supervision or mentorship. All authors read and approved the final manuscript.

Disclosure statement

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Data availability statement

The data underlying this article will be shared upon reasonable request to the corresponding author.

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